# Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/AU05/000067

International filing date: 21 January 2005 (21.01.2005)

Document type: Certified copy of priority document

Document details: Country/Office: AU
Number: 2004900302
Filing date: 22 January 2004 (22.01.2004)

Date of receipt at the International Bureau: 08 February 2005 (08.02.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

PCT/AU2005/000067

**Australian Government**

**Patent Office**
**Canberra**

I, JANENE PEISKER, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2004900302 for a patent by AUSTRALIAN SURGICAL DESIGN AND MANUFACTURE PTY LIMITED as filed on 22 January 2004.

WITNESS my hand this
Second day of February 2005

JANENE PEISKER
TEAM LEADER EXAMINATION
SUPPORT AND SALES

# AUSTRALIA

# Patents Act 1990

**Australian Surgical Design and Manufacture Pty Limited**

## PROVISIONAL SPECIFICATION

*Invention Title:*

*Heart valve*

The invention is described in the following statement:

## Technical Field

The present invention relates to the field of devices for replacing the function of a valve in the cardio-vascular system, in particular the major valves of the heart.

## Background Art

Valves of the heart are currently replaced either by artificial valves of a range of designs or animal tissue valves, with or without some artificial material incorporated. Both artificial valves using artificial materials and biological materials have shortcomings.

Shortcomings of artificial valves include the need for lifelong anti-coagulation to prevent the formation of clots in the eddies formed by the mechanical function of the valves, potential for mechanical wear and/or failure, release of wear debris into the bloodstream, excessive noise and difficulties encountered during implantation. Further shortcomings include destruction of red blood cell cells as blood passes through such mechanical valves.

Tissue valves suffer from the shortcomings of difficulty of manufacturing processes, the requirement to harvest the tissue, the need to treat the tissue to prevent the transmission of infective agents, degradation of the tissue with time through either immune response or calcification and difficulties encountered during implantation.

The present inventor has identified short comings within the prior art and has developed a device which seeks to alleviate some of the short failings.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

In a first aspect, the present invention is a valve assembly for implantation in the cardio-vascular system of a patient, the valve assembly comprising:

a support ring having an outer surface and an inner surface, the outer surface being engageable with the wall of a vessel of the patient; and

a valve body comprising an annular body portion supporting a plurality of moveable leaflets that are moveable relative to the annular body portion and to each other between a first closed position and at least one second open position defining a first fluid pathway through the assembly when subject to a first pressure differential across the body;

wherein the annular body portion is mountable to the inner surface of the support ring and is relatively rotatable thereto.

In a first embodiment of the first aspect, the moveable leaflets are a plurality of multi-sided leaflets that extend inwardly and away from the body portion.

In a second embodiment of the first aspect, the annular body portion is relatively moveable with respect to the support ring from a sealed position to at least one unsealed position defining a second fluid pathway through the assembly when the assembly is subject to the first pressure differential.

In a second aspect, the present invention is a valve assembly for implantation in the cardio-vascular system of a patient, the assembly comprising:

a valve body comprising an annular body portion supporting a plurality of multi-sided leaflets that extend inwardly and away from the body portion;

wherein said leaflets are moveable relative to the annular body portion and each other between a first closed position and at least one second open position defining a first fluid pathway through the assembly when subject to a first pressure differential across the body.

In a first embodiment of the second aspect, the assembly further comprises a support ring having an outer surface and an inner surface, the outer surface being engageable with the wall of a vessel of the patient and the annular body portion being mountable to the inner surface of the support ring.

In a second embodiment of the second aspect, the annular body portion is relatively rotatable with respect to the support ring.

In a third embodiment of the second aspect, the annular body portion is mountable to the inner surface of the support ring and is relatively moveable from a sealed position to at least one unsealed position defining a second fluid pathway through the assembly when the assembly is subject to the first pressure differential.

According to a third aspect, the present invention is a valve for implantation in the cardio-vascular system of a patient, the assembly comprising:

a support ring having an outer surface and an inner surface, the outer surface being engageable with the wall of a vessel of the patient; and

a valve body comprising a annular body portion supporting a plurality of leaflets that are moveable relative to the annular body portion and to each other, the leaflets being moveable between a first closed position and at least one second opened position defining a first fluid flow pathway through the assembly when subject to a first pressure differential across the body;

wherein the annular body portion is mountable to the inner surface of the support ring and is relatively moveable from a sealed position to at least one unsealed position defining a second fluid pathway through the assembly when the assembly is subject to the first pressure differential.

In a first embodiment of the third aspect, the moveable leaflets are a plurality of multi-sided leaflets that extend inwardly and away from the body portion.

In a second embodiment of the third aspect, the annular body portion is relatively rotatable with respect to the support ring.

In another embodiment of the first, second and third aspects, the plurality of leaflets move toward the first position upon application of a second pressure differential.

In an embodiment of the first, second and third aspects, at least one of the moveable leaflets is arranged such that upon subject to the first pressure differential across the valve body, blood flow through the first fluid pathway causes the annular body portion to rotate with respect to the support ring. Alternatively, at least a portion of the annular body portion may be arranged such that upon subject to the first pressure differential across the valve body, blood flow through the first fluid pathway causes the annular body portion to rotate with respect to the support ring.

Preferably the moveable leaflets are inclined at an angle to the direction of blood flow through the first fluid pathway and have at least a surface portion such that flow of blood past the at least a surface portion causes the moveable leaflets and the annular body portion to rotate with respect to the support ring. The surface portion may be convex, concave and/or a tip or a edge of at least one of the moveable leaflets or alternatively a protrusion extending from the moveable leaflets. Preferably the moveable leaflets may be provided with a surface coating or a surface treatment so as to at least reduce turbulence of blood flowing past and/or over the leaflets. Preferably at least a portion of the surface of at least some of the leaflets is provided with a relative roughness factor or surface texture which enhances reduction of turbulence of blood at and adjacent the surface of the leaflets.

Preferably, upon application of the first pressure differential, the first flow pathway through the valve assembly is provided by a combination of the movable leaflets moving to the at least one second position and by the moveable leaflets rotating with respect to the support ring.

In a further embodiment of the first, second and third aspects, the plurality of leaflets move toward the second position progressively upon progressive change of pressure from the second pressure differential to the first pressure differential.

In yet another embodiment of the first, second and third aspects, the plurality of leaflets move toward the first position progressively upon progressive change of pressure from the first pressure differential to the second pressure differential.

In yet a further embodiment of the first, second and third aspects, the second fluid pathway is provided between the inner surface of the support ring and the annular body portion of the valve body. Alternatively, the second fluid pathway is provided by apertures extending through the annular body portion which are sealingly engaged with the inner surface of the support ring until application of the first pressure differential.

Preferably, upon application of the first pressure differential, the annular body portion of the valve body moves in the first direction so as to provide the second fluid pathway; and upon application of the second pressure differential, the annular body portion of the valve body moves in the second direction so as to occlude blood flow through the second fluid pathway valve in the second direction.

Preferably, the annular body portion of the valve body moves in the second direction progressively upon progressive change of pressure from the first pressure differential to the second pressure differential. More preferably, the annular body portion includes a plurality of furrows located at an outer peripheral edge of the annular body portion, wherein the blood flow through the second fluid pathway further causes the valve body to rotate relative to the support ring upon application of the first pressure differential.

In still another embodiment of the first, second and third aspects, the support ring and the annular body portion form a hydrodynamic bearing lubricatable by blood of the patient.

In still a further embodiment of the first, second and third aspects, the moveable leaflets are hingedly engaged with the annular body portion of the valve body such that the plurality of moveable leaflets move from the first position toward the second position upon application of the first pressure, and to the first position upon application of the second pressure differential.

In still yet another embodiment of the first, second and third aspects, each of the plurality of moveable leaflets are affixedly engaged with the annular body portion of the valve body and are formed from a deformable material such that the plurality of moveable leaflets move from the first position toward the second position upon application of the first pressure, and to the first position upon application of the second

pressure differential. The moveable leaflets may be integrally formed with the annular body portion or alternatively the moveable leaflets may by formed separately from the annular body portion. The moveable leaflets may further include a hinged portion to as to allow the leaflets to move toward the first position and the second position. Alternatively, the moveable leaflets may biased so as to assume the second position in the absence of the first pressure differential.

In still yet a further embodiment of the first, second and third aspects ,the moveable leaflets are inclined to the longitudinal axis of the vascular vessel and extend from the annular body portion of the valve body in the first direction, and each moveable leaflet overlaps at least one adjacent leaflet when moved to the first position so as to occlude blood flow.

Preferably each moveable leaflet is generally triangular in shape. A first edge of each moveable leaflet can be engaged with the annular body portion of the valve body, and a central tip of each moveable leaflet can be positioned distal the annular body annular portion of the valve body in the first direction. Preferably, the moveable leaflets form a convex structure extending from the annular body portion of the valve body in the first direction when in the first position, and each moveable leaflet moves radially outwardly toward the second position upon application of the first pressure differential so as to reduce the occurrence of turbulence within the blood. More preferably, the central tips of the moveable leaflets are shaped so as to further reduce the occurrence of turbulence within the blood.

In another further embodiment of the first, second and third aspects, the moveable leaflets are formed from a biological material selected from the group comprising autologous graft tissue, allograft tissue and xenograft tissue.

In yet another further embodiment of the first, second and third aspects, the moveable leaflets are formed from an artificial material selected from the group comprising polymers, composites, metals and metal alloys. More preferably the moveable leaflets are formed from Nitinol™.

In still yet another further embodiment of the first, second and third aspects, the support ring is formed from a ceramic, a metal or a metal alloy material. More preferably, the support ring is formed from a Cobalt-Chromium alloy.

In still yet another further embodiment of the first, second and third aspects, the body annular portion of the valve body is formed from a ceramic, a metal or a metal alloy material. More preferably the annular portion of the valve body is formed from a Cobalt-Chromium alloy.

In an alternate embodiment of the first, second and third aspects, the support ring and/or the annular portion of the valve body includes a coating, wherein the coating is at least one of the group comprising an antibacterial coating, an anti-coagulant coating, and an anti-tissue on-growth coating, or combinations thereof.

In another alternate embodiment of the first, second and third aspects, the first pressure differential corresponds to systole of a patient's heart, and the second pressure differential corresponds to diastole.

In a fourth aspect, the present invention is a method of implanting a valve assembly within the cardio-vascular system of a patient; the method comprising the steps of:

(i) delivering the valve assembly as defined herein to a surgical site within a vascular vessel of the patient.

In a first embodiment of the fourth aspect, the support ring is delivered separately to the valve body. Preferably, the valve body is delivered to the surgical site and engaged with the support ring once the support ring is securely seated within the vascular vessel of the patient.

In a second embodiment of the fourth aspect, the support ring is delivered to the surgical site through a catheter and/or the valve body is delivered to the surgical site through a catheter.

Brief Description of the Drawings

By way of example only, preferred embodiments of the invention are now described with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of one embodiment of the cardio-vascular valve of the present invention;

Figures 2(a)-(f) are perspective, side and plan views of the valve body of the present invention;

Figures 3(a) and 3(b) are side views of the cardio-vascular valve of Figure 1;

Figures 4(a)-(d) are side views of a further example of the cardio-vascular valve in accordance with the present invention; and

Figures 5(a) and (b) are enlarged part-sectional views of the valve assembly of Figure 4.

Detailed Description of the Drawings

As shown in Figure 1, a valve assembly 10 for the cardio-vascular system of a patient according to the present invention includes a support ring 20 having an outer annular portion 21 for engagement with the inner peripheral wall of a vascular vessel of a patient and an inner annular portion 22. A valve body 30 is supported by the ring 20 and comprises an annular body portion 31 that is rotatably engageable with the inner annular portion 22 of the support ring 20 and a plurality of moveable leaflets 32.

Figure 2 depicts an example of the valve body 30 of the present invention. Figure 2(a) depicts the leaflets 32 in the first or closed position 34 while Figure 2(b) shows the moveable leaflets in a second or open position 35. A side view of the valve body 30 is shown in Figures 2(c) and 2(d) wherein the moveable leaflets 32 are again shown in the first or closed position 34 and in the second or closed position 35. Figures 2(e) and 2(f) provide a plan view of the valve body 30 with again the moveable leaflets 32 being in the first or closed position 34 and in the second or open position 35.

An example of the operation of the valve body 30 is depicted by Figure 3(a) and 3(b). When in the second or open position 35, as shown in Figure 3(b), the moveable leaflets 32 provide a first fluid pathway denoted by the arrow 33 throughout the valve assembly 10, and when the leaflets 32 are in the first or closed position 34, the moveable leaflets 32 work together to occlude the first fluid pathway 33 as shown in

Figure 3(a), occluding blood flow through the valve in the opposite direction as shown by the arrow denoting the direction of flow through the first fluid pathway 33.

In this example, the moveable leaflets 32 are arranged such that upon subject to the first pressure differential across the valve body, blood flow through the first fluid pathway 33 causes the annular body portion 31 to rotate with respect to the support ring 20. The inclination of the leaflets 32 inclined to the direction of blood flow through the first fluid pathway 33 are caused to rotate and in turn rotate the annular body portion 31 with respect to the support ring 20 as blood flows past the leaflets 32 through the first fluid pathway 33. Alternatively the leaflets 32 may include a surface portion which may be a convex, concave, tip, edge of at least one of the moveable leaflets or protrusion extending from the moveable leaflets which causes the annular body portion 31 to rotate as blood flows through the first fluid pathway 33. It is also envisaged that the relative rotational motion between the annular body portion 31 and the support ring may be caused by blood flowing past an inclined surface of the annular body portion 31, or a combination of both blood flowing past an inclined surface of the annular body portion 31 and a surface of the leaflets 32.

The plurality of moveable leaflets 32 are configured such that they move toward the second or open position 35 progressively upon progressive change of pressure from the first pressure differential to the second pressure differential. As the blood flow reduces at the end of systole the momentum of the rotating valve would then tend to start closing down as it drove against the relatively slower moving blood. As the blood flow ceases, momentarily before the pressure is exerted backwards on the valve, the moveable leaflets 32 are relatively close to the first or closed position 34 to occlude the first fluid pathway 33. This compares to all other valves where there is the moment at which shutting commences, so that the fall back pressure and leak is therefore higher and noisier as the valve snaps shut. This "snapping shut" is the cause of normal heart sounds in well functioning valves.

The plurality of moveable leaflets 32 may be hingedly engaged with the annular body portion 31 of the valve body 30 such that the plurality of moveable leaflets 32 are moveable from the first or closed position 34 toward the second or opened position 35 upon application of the first pressure differential across the valve assembly 10, and to the first or closed position 34 upon application of the second pressure differential.

Alternatively, the plurality of moveable leaflets 32 may be affixedly engaged with the annular body portion 31 of the valve body 30 and be formed from a deformable material such that the plurality of moveable leaflets 32 move from the first position 34 toward the second position 35 upon application of the first pressure, and to the first position 34 upon application of the second pressure differential.

The plurality of moveable leaflets 32 may be formed from a biological material selected from the group comprising autologous graft tissue, allograft tissue and xenograft tissue, or alternatively, the plurality of moveable leaflets 32 may be formed from an artificial material selected from the group comprising polymers, composites, metals and metal alloys, for example Nitinol™. The moveable leaflets 32 may be textured and/or coated to limit turbulence and blood clotting tendencies.

The plurality of moveable leaflets 32 may be provided with a surface coating or a surface treatment so as to at least reduce turbulence of blood flowing past and/or over the leaflets. Such a surface treatment or coating may provide reduction in turbulence within blood passing through the first fluid pathway 33. At least a portion of the surface of at least some of the leaflets 32 may be provided a relative roughness factor or surface texture which enhances reduction of turbulence of blood at and adjacent the surface of the leaflets 32. Reduction of turbulence and of blood through the first fluid pathway 33 may reduce the amount of and/or necessity of the use anticoagulant compounds.

In this example, each moveable leaflet 32 is generally triangular in shape with a first edge 36 of each moveable leaflet being engaged with the annular body portion 31 of the valve body 30, and a central tip 37 of each moveable leaflet being positioned distal the annular body portion 31 of the valve body 30 in the first direction 43. The plurality of moveable leaflets 32 form a convex structure 38 extending from the annular body portion 31 of the valve body 30 in the first direction 43 when in the first position 34.

Each moveable leaflet 32 moves radially outwardly 42 toward the second position 35 upon application of the first pressure differential so as to reduce the occurrence of turbulence within the blood of the vascular vessel 40. The central tips of the moveable leaflets may be shaped so as to further reduce the occurrence of turbulence within the blood.

The support ring 20 may be formed from a ceramic, a metal or a metal alloy material for example a Cobalt-Chromium alloy. The annular body portion 31 of the valve body 30 may be formed from a ceramic, a metal or a metal alloy material for example a Cobalt-Chromium alloy. The support ring 20 and/or the annular body portion 31 of the valve body 30 may include a coating for example an antibacterial, anti-coagulant or anti-tissue on-growth coating or a combination of coatings.

A further example of the cardio-vascular valve 10 and valve body 30 of Figures 1-3 is depicted in Figures 4(a)-(d). In this arrangement, a second fluid pathway 39 is provided between the inner annular portion 22 of the support ring 20 and the annular body portion 31 of the valve body 30.

Upon application of the first pressure differential, the annular body portion 31 of the valve body 30 moves in the first direction 33 so as to provide the second fluid pathway 39 in addition to the first fluid pathway 33 as shown in Figure 4(b), and upon application of the second pressure differential, the annular body portion 31 of the valve body 30 moves in a second direction 44 so as to occlude blood flow through the second fluid pathway 39 in the second direction 44 as shown in Figure 4(a). The annular body portion 31 of the valve body 30 moves in the second direction 44 progressively upon progressive change of pressure from the first pressure differential to the second pressure differential.

An example of the cardio-vascular valve of Figures 4(a) and 4(b) when engaged with the wall of a vascular vessel 40 of a patient is provided in Figures 4(c) and 4(d). In this example, each of the plurality of moveable leaflets 32 are inclined to the longitudinal axis 41 of the vascular vessel 40 and extend from the annular body portion 31 of the valve body 30 in a first direction 43, and each moveable leaflet 32 overlaps at least on adjacent leaflet when moved to the second position 35 so as to occlude blood flow.

Figure 5(a) is an enlarged part-sectional view of the valve assembly 10 of Figure 3. In this example, the annular body portion 31 may include a plurality of furrows 45 located at an outer peripheral edge 46 of the annular body portion 31 such that blood flow through the second fluid pathway 39 further causes the valve body 30 to rotate relative to the support ring 20 upon application of the first pressure differential.

The support ring 20 and the annular body portion 30 may form a hydrodynamic bearing lubricatable by blood of the patient. Figure 5(b) shows a portion of the annular body portion 31 having a plurality of furrows 45 located at the outer peripheral edge 46 of the annular body portion 31.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

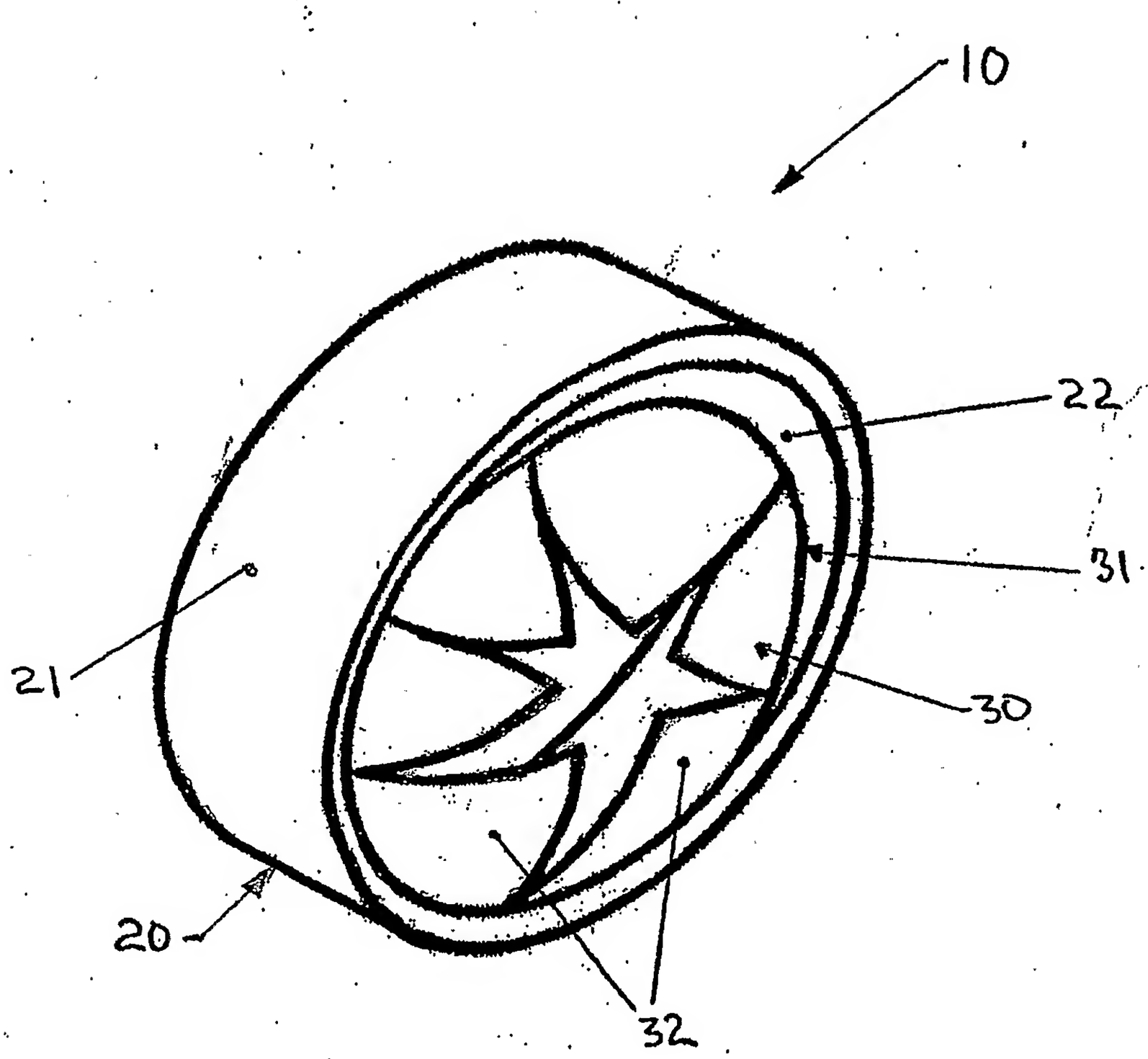



Figure 1

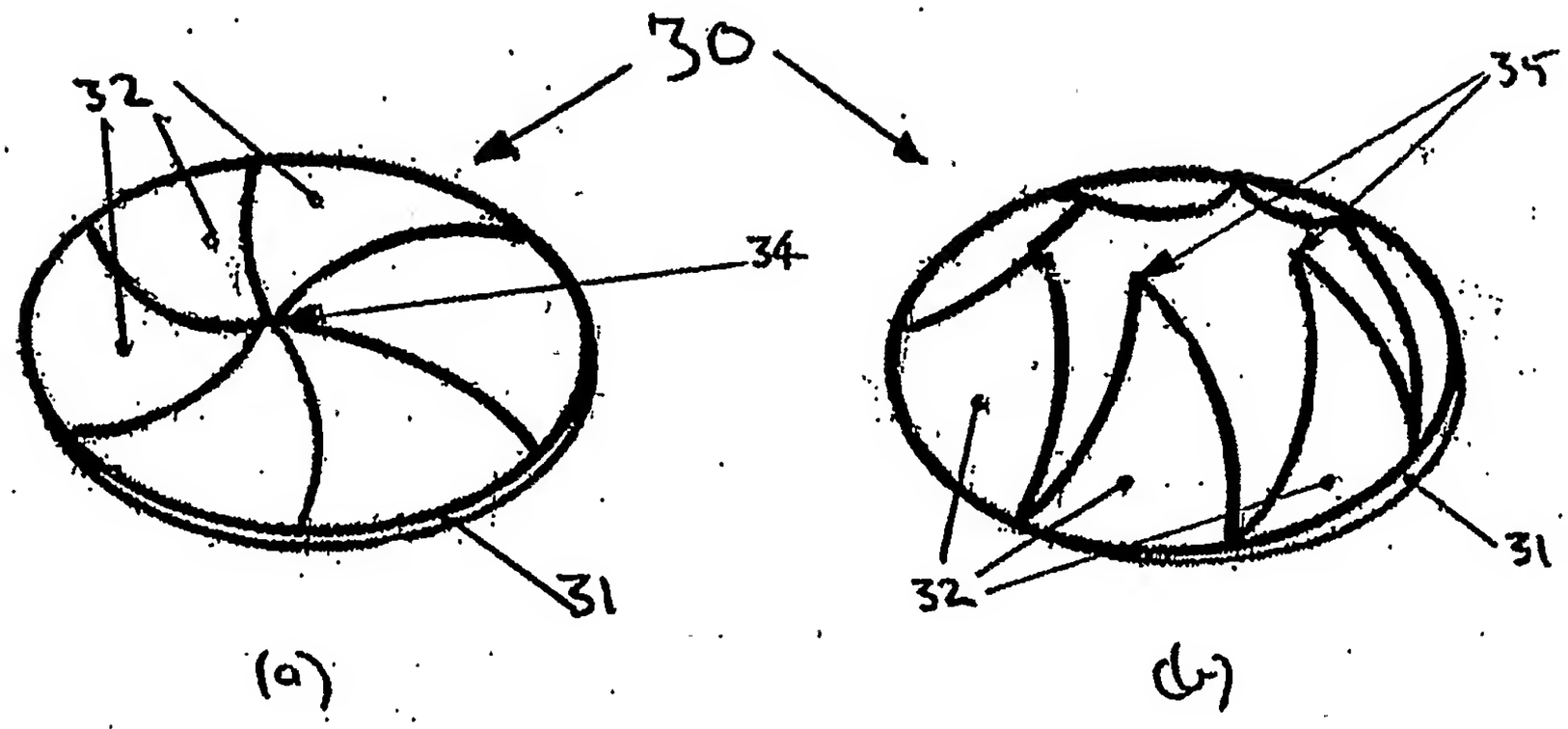



Figure 2

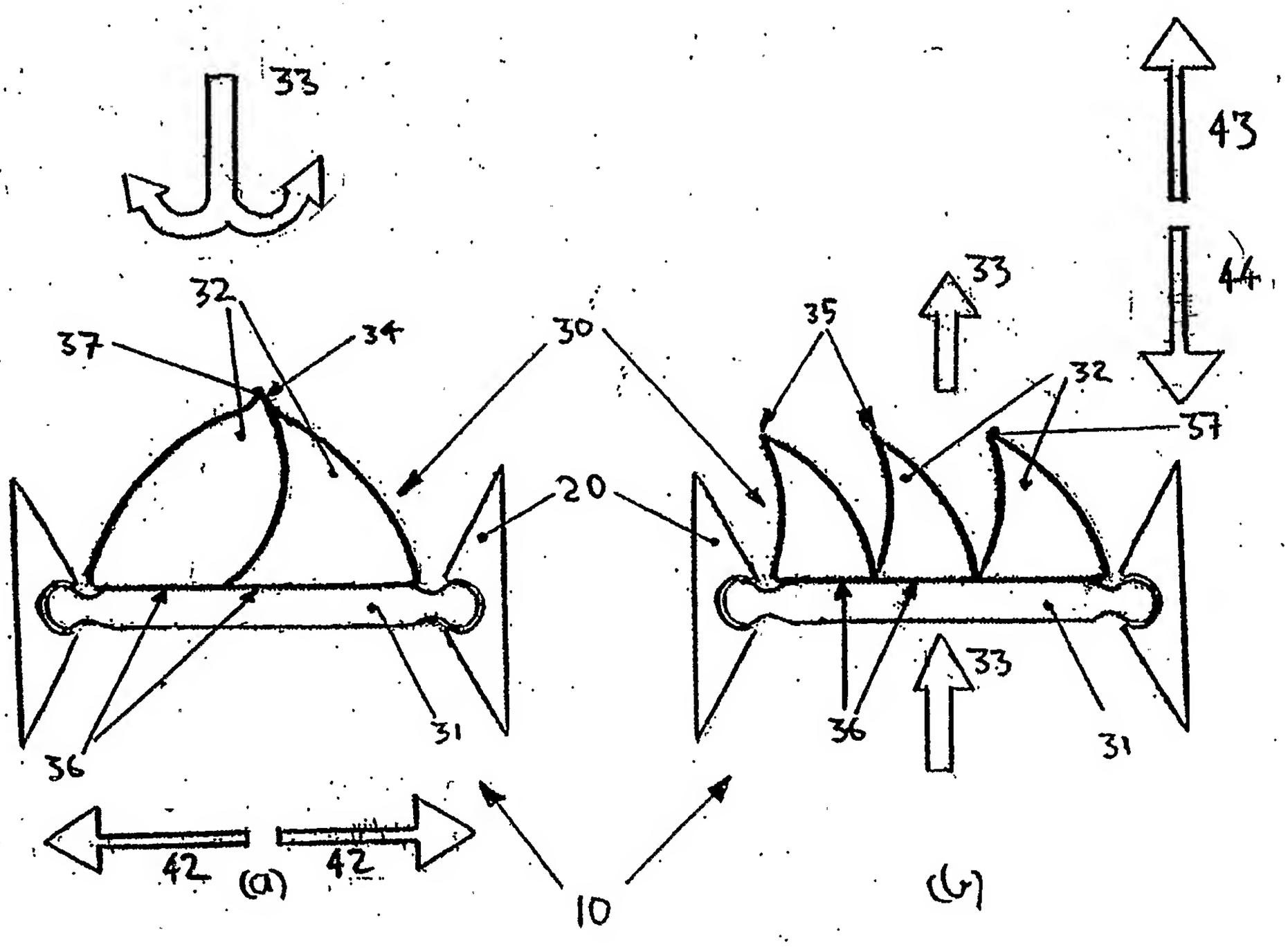
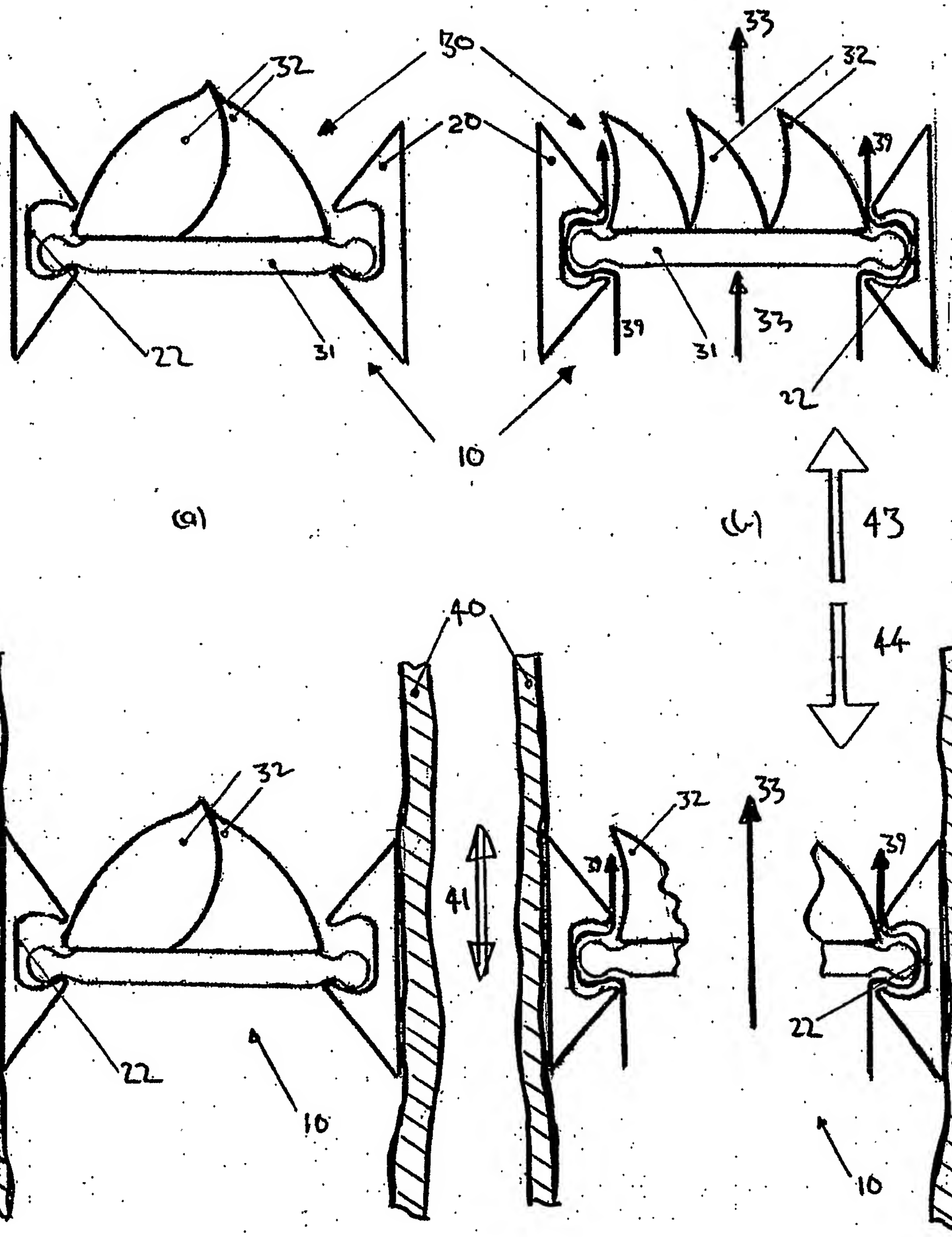


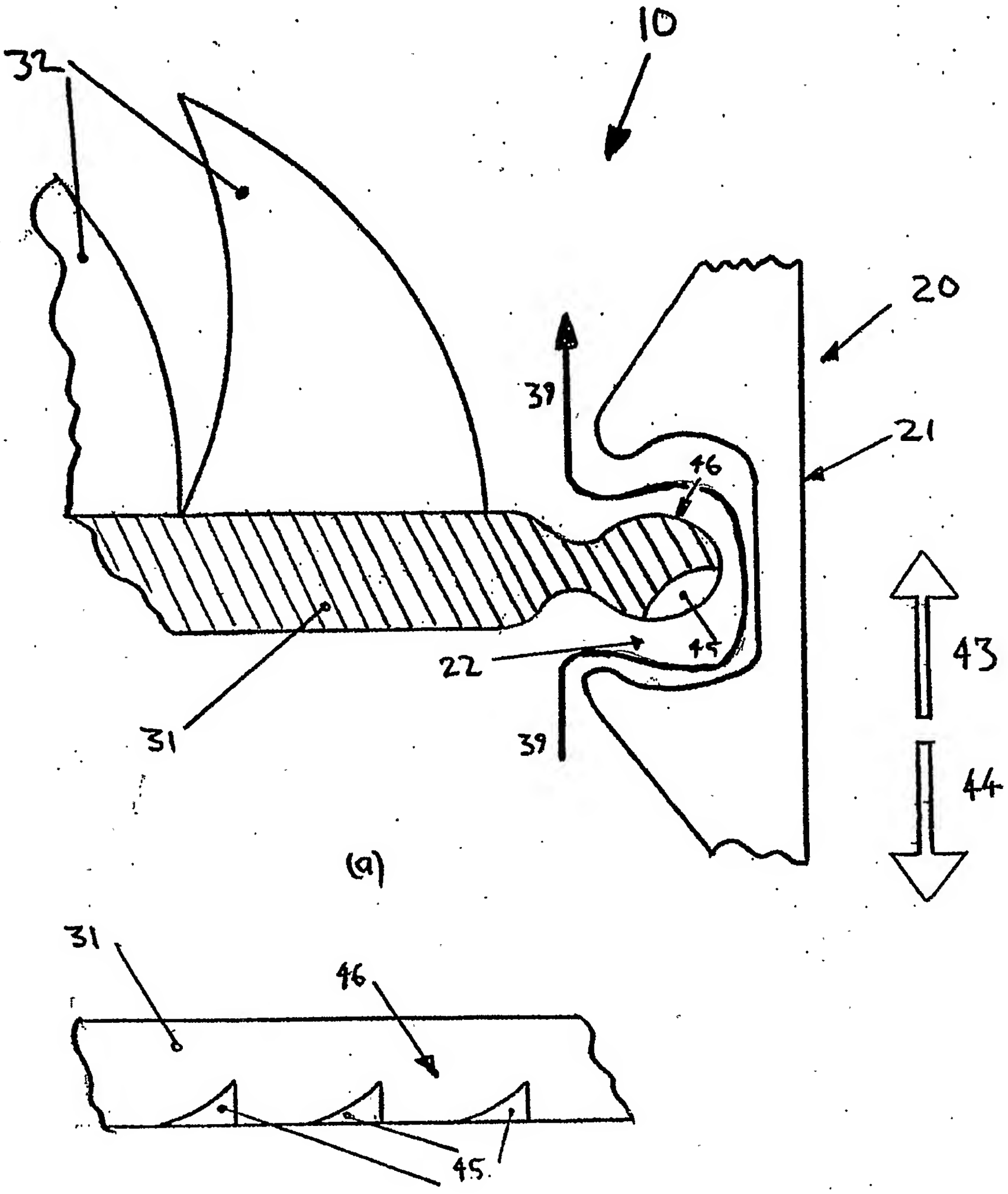

Figure 3




(a) (b)

(c) (d)

Figure 4




(a)




(b)

Figure 5